5/27/05

MAY 2 7 2005 2

PTO/SB/08a/b (08-03)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

or the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Complete If Known for form 1449A/B/PTO Application Number 10/827,309 INFORMATION DISCLOSURE Filing Date April 20, 2004 STATEMENT BY APPLICANT First Named Inventor Michael B. Zemel Art Unit 3622 (Use as many sheets as necessary) **Daniel Lastra** Examiner Name Sheet Attorney Docket Number 31894-199326

	U.S. PATENT DOCUMENTS							
Examiner	C11-	Document Number	Publication Date	Name of Patentee or	Pages, Columns, Lines, Where			
Initials*	Cite No.1	Number-Kind Code ² (#known)	101001000	Applicant of Cited Document	Relevant Passages or Relevant Figures Appear			
II L	AA	US-6,384,088-B1	05-07-2002	Hinz				

		FOREIG	ON PATENT	DOCUMENTS		
Examiner Initials*	Cite No.	Foreign Patent Document Country Code ³ -Number -Kind Code ⁴ (il known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	
				· 		Γ

*EXAMINER: tritial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. Applicants unique citation designation number (optional). See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. Enter Office that issued the document, by the two-latter code (WIPO Standard ST.3). For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. Name of the patent document of the patent document with the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. Applicant is to place a check mark here if English language Translation is attached.

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
OL CA		Garrow, J.S., et al., "Inpatient-Outpatient Randomized Comparison of Cambridge Diet Versus Milk Diet in 17 Obese Women Over 24 Weeks," International Journal of Obesity , 13: 521-529 (1989).	
	СВ	McCarron, David A., et al., "Blood Pressure and Nutrient Intake in the United States," Science 224:1392-1398 (1984).	
	CC	Metz, J.A., et al., "Modification of Total Body Fat in Spontaneously Hypertensive Rats and Wistar-Kyoto Rats by Dietary Calcium and Sodium," <i>American Journal of Hypertension, Inc.</i> 1:58-60 (1988).	
	CD	Skinner, J., et al., "Does Dietary Calcium Have a Role in Body Fat Mass Accumulation in Young Children?," Nutrition, suppl no 34, pp 45S (1999).	
	CE	Summerbell, Carolyn D., et al., "Randomised Controlled Trial of Novel, Simple, and Well Supervised Weight Reducing Diets in Outpatients," BMJ 317:1487-1489 (1998).	
	CF	Teegarden, D., et al., "Calcium Intake Relates to Change in Body Weight in Young Women," The FASEB Journal 13:A873, Abstracts Part II No. 660.4 (1999).	
V	CG	Zemel, Michael B., "Nutritional and Endocrine Modulation of Intracellular Calcium: Implications in Obesity, Insulin Resistance and Hypertension," <i>Molecular and Cellular Biochemistry</i> 188:129-136 (1998).	_

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Examiner Signature Date Considered 6/12/65

^{&#}x27;Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached. 651465v1

Please type a plus sign (+) inside this box	+
---	---

4/20/04

PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
prespond to a collection of information unless it contains a valid OMB control number.

Substitut	e for form 1449A/PTC)		Complete if Known			
_				Application Number	Not Yet Assigned		
INFORMATION DISCLOSURE				Filing Date	April 20, 2004		
STATEMENT BY APPLICANT			PPLICANT	First Named Inventor	Michael B. ZEMEL et al.		
				Group Art Unit	Not Yet Assigned		
_	(use as many she	ets as	necessary)	Examiner Name	Not Yet Assigned		
Sheet	1	of	5	Attorney Docket Number	31894-199326		

U.S. PATENT DOCUMENTS							
Examiner Initials *	a	U.S. Pater	nt Document	Name of Patentee or Applicant	Date of Publication of	Pages, Columns, Lines, Where Relevant	
	Cite No.'	I Niimner	Kind Code ² (if known)	of Cited Document	Cited Document MM-DD-YYYY	Passages or Relevant Figures Appear	
7)4	Al	6,384,087	7	ZEMEL et al.	05-07-2002		
DL	A2	3,621,024	4	NIEPER	11-16-1971		
DL	A3	5,914,326	6	MCCARTY et al.	06-22-1999		
DL	A4	6,136,349	9	KARPPANEN et al.	10-24-2000		
DL	A5	6,071,544	4	SUNVOLD	06-06-2000		
			[
			1			† · · · · · · · · · · · · · · · · · · ·	

				FOREIG	ON PATENT DOCUME	NTS		
Examiner Initials*		Fore	ign Patent Doc	ument	Name of Patentee or	Date of	Pages, Columns, Lines,	
	Cite No.1	Office ³	Number ⁴	Kind Code ⁵ (if known)	Applicant of Cited Document	Publication of Cited Document MM-DD-YYYY	Where Relevant Passages or Relevant	, То
Ðζ	A6	BE	723,952	1	NIEPER	04-16-1969		
DL	A7	wo	98/28989		KARPPANEN	07-09-1998		
DL	A8	wo	99/03464		GANGA	01-28-1999		
DL	A9	wo	99/11254		OCTROOIBUREAU	03-11-1999		
		 	-	-				
			2	2				

Examiner Signature	Man//10	Date Considered	6/12/05

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandra, VA 22313-1450.





¹ Unique citation designation number. 2 See attached Kinds of U.S. Patent Documents, 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. • Applicant is to place a check mark here if English language Translation is attached.

Please type a	olus sian (+) inside this	\rightarrow	+
LICOSC INDO O	mas signi (.	,	~~	

PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0851-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO Complete if Known **Application Number** Not Yet Assigned INFORMATION DISCLOSURE Filing Date April 20, 2004 STATEMENT BY APPLICANT First Named Inventor Michael B. ZEMEL et al. Group Art Unit Not Yet Assigned (use as many sheets as necessary) **Examiner Name** Not Yet Assigned of 5 Sheet **Attorney Docket Number** 31894-199326

		OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS	
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T 2
DL A10		BÖRJESON, M. [1976] "The actiology of Obesity in Children, " Acta Paediatr Scan 65:279-87	
İ	All	CARPER, JEAN [2000] "Amazing Food Facts That Astound the Experts, " USA Weekend, Aug. 18-20, 2000, p. 4	
	A12	CNN, "Zemel Weight Loss Story, March 30, 2000; and NATIONAL DAIRY COUNCIL, "Diary Foods May Help Control Weight Gain," June 9, 2000, videotape	
	A13	COLINO, S., "Advanced Calcium, Lose Weight, avoid PMS and ward off cancer, all with one basic nutritional element, " Women's Sports & Fitness, March 2000, page 56	
	A14	DAVIS, J.; "Weight-Loss Tip: Add Extra Calcium to a Low-Fat Diet, Low-Fat Diary Products May Help Weight Loss, Control," WebMDHealth, April 17, 2000 (printed from website), Publisher: 2000 Healtheon/WebMD	
	A15	FLEET, J.C. [1999] "Vitamin D. Receptors: Not Just in the Nucleus Anymore," Nutrition Reviews Vol. 57, No. 2, pp.60-2	-
	A16	FLEURY, CHRISTOPHE, et al. [1997] "Unoupling Protein-2: a Novel Gene Linked to Obesity and Hyperinsulinemia," Nature Genetics 15:269-72	
	A17	Gimeno, R. et al. [1997] "Cloning and Characterization of an Uncoupling Protein Homolog: A Potential Molecular Mediator of Human Thermogenesis," Diabetes 46:900-06	
	A18	JONES, BRYNN H., et al. [1997] "Angiotensin II Increase Lipogenesis in 3T3-L1 and Human Adipose Cells," Endocrinology, Vol. 138, No. 4, pp. 1512-19	
	A19	KIM, JUNG HAN et al. [1996] "The Effects of Calcium Channel Blockade on Agouti-Induced Obesity", The FASEB Journal 10:1646-52	
V .	A20	LANGE, D., "The Calcium Diet", Allure, August 2000, page 84	

Examiner Signature	14/11/11/11	Date Considered	6/12/05	
			0112,000	

EXAMINER: Initiacit reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

¹ Unique citation designation number. 2 Applicant is to place a check mark here if English language Translation is attached.

4/20/04

Please type a plus sign (+) inside this box	
Please type a plus sign (+) inside this boy	T
icoso type o pies agri (-) riiside das oux	

Sheet

PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0651-0031 U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE
STATEMENT BY APPLICANT

Fine

Green

(use as many sheets as necessary)

of 5

Complete if Known	
Not Yet Assigned	
April 20, 2004	
Michael B. ZEMEL et al.	
Not Yet Assigned	
Not Yet Assigned	
31894-199326	
	Not Yet Assigned April 20, 2004 Michael B. ZEMEL et al. Not Yet Assigned Not Yet Assigned

		OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS	
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
DL	A21	MASLOWSKA, M. et al. [1998] "Site Specific Binding of Acylation Stirmulating Protein (ASP) in Human Adipose Tissue," Int. J. Obesity 22:S108 (P50)	
	A22	McCarty, L., "Got Milk, Lose Weight?," Remedy Magazine, March/April 2000, page 11	
	A23	MOLL, P.P., et al. [1991] "The Genetic and Environmental Sources of Body Mass Index Variability: The Muscatine Ponderosity Family Study," Am. J. Hum. Genet. 49:1243-55.	
	A24	MUNDELL, E.J., "Trying to Lose Weight? Calcium May Help", Reuters health report, April 17, 2000, (printed from website), Publisher: Reuters Limited	
	A25	MYNATT, R.L., et al. [1997] "Combined Effects of Insulin Treatment and Adipose Tissue-Specific Agouti Expression on the Development of Obesity," Proc. Natl. Acad. Sci. USA 94:919-922	
	A26	NEMERE, I., et al. [1998] "Identification of a Membrane Receptor for 1, 25-Dihydroxyvitamin D, Which Mediates Rapid Activation of Protein Kinase C," J. of Bone and Mineral Research 13:1353-59	
	A27	PANTALONE, M., "Hello Calcium, Goodbye Fat," UT Agriculture, Fall 2000, Pages 5-7	
	A28	RABKIN, R., "Calcium Promotes Weight Loss," Family Circle, October 3, 2000, page 98	
	A29	RALOFF, J., "Calcium May Become a Dieter's Best Friend," Science News, April 29, 2000, page 277, Vol.157	
	A30	SHJ, HANG, et al. [1999] "Role of the Sulfonylurea Receptor in Regulating Human Adipocyte Metabolism," The FASEB Journal 13:1833-38	
1	A31	SHI, H. et al. [2000] "Effects of Dietary Calcium on Adipocyte Lipid Metabolism and Body Weight Regulation in Energy- Restricted Mice," FASEB J 14:555.3 (page A790)	

Examiner Signature	11-111 MIO	Date Considered	6/12/08
	111 700/11 000		

EXAMINER: Initially reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

VENABLE

¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.

4/20104

Please type a plus sign (+) inside this box —	+	ı
---	---	---

PTO/SB/08A (08-00)

Approved for use through 10/31/2002, OMB 0651-0031 U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO Complete if Known **Application Number** Not Yet Assigned INFORMATION DISCLOSURE Filing Date April 20, 2004 STATEMENT BY APPLICANT First Named Inventor Michael B. ZEMEL et al. Group Art Unit Not Yet Assigned (use as many sheets as necessary) **Examiner Name** Not Yet Assigned of 5 Sheet Attorney Docket Number 31894-199326

OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS				
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²	
DC	A32	SHI, H. et al. [2000] "1, 25-Dihydroxyvitamin D (1, 25-(OH) ₂ -D) Inhibits Uncoupling Protein 2 (UCP2) Expression in Human Adipocytes," Obesity Research 8(1):52S (O154)	-	
	A33	SHI, H. et al. [2001] "Effects of Dietary calcium on Adipocyte Lipid Metabolism and Body Weight Regulation in Energy- Restricted aP2-agouti Transgenic Mice," FASEB J 15:291-3 and 10.1096/fj.00-0584fje		
	A34	SHI, H. et al. [2001] "1a, 25-Dihyroxyvitamin D, Modulates Human Adipocyte Metabolism via Nongenomic Action," FASEB J 15:835.6 (page A1091)		
	A35	SMITH, S., "Functional Foods Potential New Functional Qualities of Dairy Foods," NCC Newsletter, 2001, pages 34-5, Vol. 3, issue 2; Publisher: Nutrition in Complementary Care		
	A36	SOBEL, R.K. [2000] "Catching the Fat Bug," U.S. News & World Report p. 64		
	A37	SUMMERBELL, C.D., et al. [1998] "Randomised Controlled Trial of Novel, Simple, and Well Supervised Weight Reducing Diets in Outpatients," BMJ 317:1487-89		
	A38	Unknown, "5-Step Fat-Blasting Diet," Prevention Magazine, June 2000, page 151		
	A39	Unknown, "Calcium and Weight-Loss," Medizine, Jan-Feb-Mar 2001, page 52		
	A40	ZEMEL, M. et al. [1999] "Calcium and Calcium-Rich Dairy Products Reduce Body Fat," FASEB J 12:LB211		
	A41	ZEMEL, M. et al. [1999] "Synergistism between Diet-induced Hyperinsulinemia and Adipocyte-Specific Agouti Expression," FASEB J 13:660.3 (page A873)		
V	A42	ZEMEL, M., "Readers Want to Know," Bottom Line/Health, October 2000		

Examiner Signature	BAL///2	Date Considered # 6/12/05	

EXAMINER: Injuite if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered, include copy of this form with next communication to applicant.

SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.



¹ Unique citation designation number. 2 Applicant is to place a check mark here if English language Translation is attached.

4/20/04

Please type a plus sign (+) inside this box $ ightarrow$	+	I
--	---	---

PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO Complete if Known **Application Number** Not Yet Assigned INFORMATION DISCLOSURE Filing Date April 20, 2004 STATEMENT BY APPLICANT First Named Inventor Michael B. ZEMEL et al. **Group Art Unit** Not Yet Assigned (use as many sheets as necessary) **Examiner Name** Not Yet Assigned Sheet of 5 **Attorney Docket Number** 31894-199326

Examiner nitials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T 2
FC A43 ZE		ZEMEL, M. et al. [2001] "Effects of Calcium-Fortified Breakfast Cereal on Adiposity in a Transgenic Mouse Model of Obesity," FASEB J 15:480.7 (page A598)	
	A44	ZEMEL, M. B. et al. [2000] "Regulation of Adiposity by Dietary Calcium," The FASEB Journal, Vol. 14, No. 9, pp. 1132-7	
	A45	ZEMEL, P. et al. [2000] "Increasing Dietary Calcium and Dairy Product Consumption Reduces the Relative Risk of Obesity in Humans," Obesity Research 8(1):118 (HT-04)	
	A46	SANWA KAGAKU KENKYUSHO CO, "Stabilised Oligo Peptide Composition for Sleep-Improving Drug Containing Oligo-Peptide and Bovine Bone Powder as Calcium Salt, for Obesity Treatment, etc.," Database WPI, Section Cb, Week 199028, Derwent Publications Ltd., London, GB; Class B04, AN 1990-214417, XP002206900 & JP 02 145525 A, June 5, 1990 - abstract	
	A47	MEIJI SEIKA KAISHA, "Food Compound for Overweight Clients - Obtained by Blending Water Soluble Dietary Fibers and Insoluble Calcium Compound in Acidic Conditions, e.g., Gastris Juice," Database WPI, Section Ch, Week 199211, Derwent Publication Ltd., London, GB; Class D13, AN 1992-083488, XP002206898 & JP 04 023968 A, January 28, 1992 - abstract	_
	A48	MEIJI SEIKA KAISHA, "Diet or Diabetic Food - Contains Water-Soluble Food Fiber, Preferably Arginic Acid (Salt), and Insoluble Calcium Compound," Database WPI, Section Ch, Week 199532, Derwent Publication Ltd., London, GB; Class B04. AN 1995-242723, XP002206899 & JP 07 147935 A, June 13, 1995 - abstract	
	A49	B. BOUILLON, et al., "Structure-Function Relationships In The Vitamin D Endocrine System," Endocrine Rev. (1995) pp. 200- 57, Vol. 16.	
	AS0	A.W. NORMAN, "Receptor for 1a,25(OH)2-D3: Past, Present, and Future," J. Bone. Miner. Res. (1998) pp. 1360-69, Vol. 13.	
V	ASI	A. NORMAN et al., "Demonstration That 18,25-Dihydroxyvitamin D3 Is An Antagonist Of The Nongenomic But Genomic Biological Response And Biological Profile Of The Three A-Ring Diastercomers Of 1a,25-Dihydroxyvitamin D3", J. Biol. Chem. (1993) pp. 20022-30, Vol. 268.	

Examiner Signature	Jen //11	Date Considered	6/12/05
	<i></i>		

EXAMINER: Initial If reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.



¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.